AUG 1 7 2000

K001580

## SUMMMARY OF SAFETY AND EFFECTIVENESS

**SPONSOR:** Biomet, Inc.
56 East Bell Drive
Warsaw IN 46582

**CONTACT PERSON:** Tina Lakin

**DEVICE NAME:** Gross Femoral Component

**CLASSIFACTION NAME:** Prosthesis, Hip, Semi-constrained, uncemented, metal/polymer, non-porous, osteophilic finish (87MEH)

**INDICATIONS FOR USE:** The Gross femoral component is indicated for use in:

1. Non-inflammatory degenerative joint disease, including osteoarthritis and avascular necrosis
2. Rheumatoid arthritis
3. Correction of functional deformity
4. Revision procedures where other treatment or devices have failed
5. Treatment in conjunction tumor resection
6. Trauma

**DEVICE DESCRIPTION:** The Gross femoral component is manufactured from wrought titanium alloy with a ribbed HA coating covering the proximal third. The device is a single use implant intended for press-fit application. The Gross femoral component is categorized as anatomic design. The device is custom fit to patients using an envelope of sizing.

**POTENTIAL RISKS:** The potential risks with this device are the same wit any other joint replacement device. These include, but are not limited to:

Fracture of component
Cardiovascular disorders
Implant loosening/migration
Soft tissue loosening
Deformity of the joint
Tissue growth failure
Delayed wound healing
Metal sensitivity
Bone fracture
Hematoma
Blood vessel damage
Nerve damage
Excessive wear
Infection
Dislocation

**SUBSTANTIAL EQUIVALENCE:** The Gross Hip component is the same in overall design and intended function to most hip components on the market. Direct comparison was made with:

-Biomet Patient-Matched Implant Hip Femoral Component: K923452 Uncemented
K911802 Cemented

-HAP Bio-Groove Total Hip Prosthesis: Biomet - K912369

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 17 2000

Ms. Tina Lakin
Regulatory Specialist
Biomet Inc.
P.O. Box 587
Warsaw, Indiana 46581

Re: K001580
Trade Name: Gross Femoral Component
Regulatory Class: II
Product Code: MEH
Dated: May 19, 2000
Received: May 22, 2000

Dear Ms. Lakin:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K001580

DEVICE NAME: Gross Hip Femoral Component

INDICATIONS FOR USE:

The Gross Hip Femoral Component is indicated for use in:

1) Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
2) Rheumatoid arthritis
3) Correction of functional deformity
4) Revision procedures where other treatment or devices have failed
5) Treatment in conjunction with tumor resection
6) Trauma

This device is a single use implant.

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vochmer

(Division Sign-Off)

neral Restorative Devices

510(k) Number K001580

Prescription Use ya OR Over-The-Counter-Use no

(Per 21 CFR 801.109)

(Optional Format 1-2-96)